



California State Board of Pharmacy

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STATE AND CONSUMER SERVICES AGENCY

DEPARTMENT OF CONSUMER AFFAIRS
GRAY DAVIS, GOVERNOR

**DEPARTMENT OF CONSUMER AFFAIRS
BOARD OF PHARMACY
NORTHERN COMPLIANCE COMMITTEE MEETING
MINUTES**

DATE: February 9, 2000

TIME: 10:00 a.m. – 12:30 p.m.

LOCATION: 400 R Street
Suite 3020
Sacramento, CA 95814

BOARD MEMBER

PRESENT: Rich Mazzoni, Chairperson
Thomas Nelson, Board Member
Robert Elsner, Board Member

STAFF

PRESENT: Robert Ratcliff, Supervising Inspector
Gilbert Castillo, Supervising Inspector
Lin Hokana, Pharmacy Inspector
Anne Sodergren, Enforcement Coordinator

ALSO

PRESENT: Jerald Bennett, RPH, PIC
Allan Harvey Gobuty, RPH
Robert Harrell, RPH, PIC
Ruth Kemper, Regional Pharmacy Manager
Christina Kao, RPH
Nancy Lee, RPH, PIC
Sageda Mahmoud, Pharmacy Development Manager
Bruce Wiswell, Pharmacy Development Manager
Lobelia Rubin, RPH, PIC
Vito Maurantonio, RPH, PIC
Leo Leal, Owner
Michael Trone, RPH, PIC
O. E. "Bud" Fox, RPH
Richard Giambruno, Owner

Northern Compliance Committee

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Paramijit Randhawa, RPH, PIC
Phillip Webb, RPH
Mark Karpoff, RPH
Priscilla Martinez, TCH
Chris Dige, Pharmacy Supervisor

CALL TO ORDER

Chairperson Rich Mazzoni called the meeting of the Northern Compliance Committee to order at 10:00 a.m.

A. DISCIPLINARY APPEARANCES

1. Jerald Bennett CI 1997 15921
RPH 21817, PIC

Allan Harvey Gobuty
RPH 24878

Robinson's Pharmacy
Placerville, CA
PHY 21802

Jerald Bennett, Allan Harvey Gobuty and Robinson's Pharmacy were requested to appear at the Northern Compliance Committee Meeting as the result of an investigation that revealed that Robinson's Pharmacy dispensed Tylenol with Codeine on a refill prescription calling for Tegretol. During the investigation additional violations of pharmacy law were determined. This investigation confirmed that Robinson's Pharmacy was not providing patient consultation as required. The pharmacy technician read the instructions to the patient from the container label. It was also observed that pharmacy staff was compounding in a non-licensed area, and that the pharmacy is not equipped with a laminar hood.

On December 7, 1998, a violation notice was issued to Robinson's Pharmacy, Jerald Bennett, and Allan Harvey Gobuty for violation of:

- Business and Professions Code section 4301 (n) – Unprofessional conduct.
- Business and Professions Code section 4113 (b) – The pharmacist-in-charge shall be responsible for a pharmacy's compliance with all state and federal laws and regulations pertaining to the practice of pharmacy.
- Business and Professions Code section 4115 (f) – The performance of duties by a pharmacy technician shall be under the direct supervision and control of a pharmacist.
- Business and Professions Code section 4110 (a) – No person shall conduct a pharmacy in the State of California unless he or she has obtained a license from the board.
- Business and Professions Code section 4037 – Pharmacy means an area, place, or premises licensed by the board in which the profession of pharmacy.
- Business and Professions Code section 4342 (a) – Actions by board to prevent sales of preparation or drugs lacking quality or strength.
- California Code of Regulations section 1716 – Variation from prescription.
- California Code of Regulations section 1707.2 (b) – Duty to consult, whenever a prescription drug not previously dispensed to a patient in the same dosage form, strength or with the same written directions is dispensed by the pharmacy.

- California Code of Regulations section 1707.3 – Duty to review drug therapy and patient medication record prior to dispensing.
- California Code of Regulations section 1714 (b) – Each pharmacy licensed by the board shall maintain its facilities, space, fixtures, and equipment so that drugs are safely and properly prepared, maintained, secured and distributed.
- California Code of Regulations section 1714 (d) – Each pharmacist while on duty shall be responsible for the security of the prescription department, including provision for effective control against theft or diversion of dangerous drugs.
- California Code of Regulations section 1717 (b) (3) – If a prescription for a drug or device is refilled, a record of each refill, quantity dispensed, if different, and the initials or name of the dispensing pharmacist.
- California Code of Regulations section 1751 – Compounding area for parenteral solutions.
- California Code of Regulations section 1764 – Unauthorized disclosure of prescriptions.
- California Code of Regulations section 1716.2 – Record requirements compounding for future furnishing.

The committee informed those present that at the time of the investigation consultation laws had been in effect for eight years. The committee questioned how it could be that the pharmacy still has no procedures in place to instruct staff on how to determine when consultation is required.

Mr. Bennett responded that the pharmacy staff had been instructed time and time again on the consultation requirements. Mr. Bennett stated that it was his fault that there were no written procedures in place, it has always been his method to write “see me” on the prescription receipt. The pharmacy now marks every new prescription with a large red “Important” to indicate consultation is required.

The committee expressed concern with regards to the non-licensed support staff reading the prescription labels to the patient.

Mr. Bennett explained that he has the support staff read the label to the patient each time to ensure that the medication is being dispensed to the correct patient, and that it is being dispensed for the correct purpose.

The committee admonished Mr. Bennett and Mr. Gobuty stating that they have abdicated their responsibility to their support staff. Reading the label to determine the appropriateness of the prescription is the responsibility of a pharmacist not a pharmacy technician or a non-licensed clerk.

Mr. Bennett explained the changes that have been made in the pharmacy with regard to installing a consultation area, with monitoring cameras so that the pharmacist can see from the filling station that a patient is waiting.

The committee instructed Mr. Bennett that he must have line of sight over the entire area. The area must be brought into compliance.

The committee expressed concern with regards to dangerous drugs being stored outside of the licensed area.

Mr. Bennett stated that the area in question is only used for compounding because there is not enough room in the pharmacy.

The committee explained that the problem is that the area in question is not contiguous to the licensed area.

Mr. Bennett responded that the area is through an opening adjacent to the current licensed area.

The committee asked those present if the pharmacy has been equipped with a laminar hood.

Mr. Bennett responded that the pharmacy does not have a laminar hood, and added that the pharmacy no longer prepares parenterals.

M/S/C: Elsner/Nelson

The committee accepted the appearance of Jerald Bennett, Allan Harvey Gobuty, and Robinson's Pharmacy; (a) the matter will be made a part of the record of Jerald Bennett, RPH 21817, Allan Harvey Gobuty, RPH 24878, and Robinson's Pharmacy, PHY 21802; (b) perform a follow up inspection will be conducted within the next six months; (c) Jerald Bennett, RPH 21817, is cited and fined \$2500, for failure to provide patient consultation as required; (d) Allan Harvey Gobuty, is cited and fined \$1000, for failure to provide patient consultation as required; (e) Robinson's Pharmacy, is cited and fined \$2500, for failure to provide patient consultation as required. No further action will be taken at this time.

2. Robert Harrell
RPH 35684, PIC

CI 1998 16059

Safeway Pharmacy #273
Anderson, CA
PHY 35684

Ruth Kemper, Regional Pharmacy Manager

Robert Harrell and Safeway Pharmacy #273 were requested to appear at the Northern Compliance Committee Meeting as the result of an investigation that revealed that PIC Harrell dispensed #1000 Levothyroxine 300mcg on two separate occasions without a prescription.

On April 28, 1999, a violation notice was issued to Robert Harrell for violation of:

- Business and Professions Code section 4301-(f) (o) – Unprofessional conduct.
- Business and Professions Code section 4059 – Furnishing dangerous drugs or devices prohibited without prescription.
- Business and Professions Code section 4040 – Prescription content requirements.

President Mazzoni recused himself from this hearing.

Mr. Harrell responded that his friend refused to take his dog to the veterinarian to obtain a prescription for Levothyroxine. Mr. Harrell stated that he knew the dog would not live very long without his medication. Mr. Harrell explained twice he gave his friend a bottle of Levothyroxine for his dog. Mr. Harrell added that at no time was the medication intended for human consumption.

The committee expressed concern as to whether or not Mr. Harrell would do it again.

Mr. Harrell responded that he has learned his lesson, he would never do it again.

M/S/C: Elsner/Nelson

The committee accepted the appearance of Robert Harrell, and Safeway Pharmacy #273; (a) the matter will be made a part of the record of Robert Harrell, RPH 35684, and Safeway Pharmacy #273, PHY 35684. No further action will be taken at this time.

3. Nancy Lee
RPH 25073, PIC

CI 1998 17574

Christina Kao
RPH 47816

Rite Aid #5893
Redwood City, CA
PHY 43940

Bruce Wiswell, Pharmacy Development Manager
Richard Martland, Attorney
Sageda Mahmoud, Pharmacy Development Manager

Nancy Lee, Christina Kao, and Rite Aid #5893 were requested to appear at the Northern Compliance Committee Meeting as the result of an investigation that revealed that Rite Aid #5893 dispensed early refills on pain medications without documentation of the agent authorizing the refills. It was also determined during this investigation that RPH Kao did not perform drug utilization reviews or document consulting with the patient or doctor.

On October 4, 1999, a violation notice was issued to Rite Aid #5893 and Christina Kao for violation of:

- Business and Professions Code section 4301(d) (o) – Unprofessional conduct.
- Business and Professions Code section 4071- Reduction of oral or electronic prescriptions to writing.
- California Code of Regulations section 1707.3 - Duty to review drug therapy and patient medication record prior to dispensing.
- Health and Safety Code section 11153 – Responsibility for legitimacy of prescription; corresponding responsibility of the pharmacist.

The committee expressed concern with regard to how Ms. Kao perceived her responsibility as the pharmacist to perform drug utilization review.

Ms. Kao responded that her normal procedure is to call the prescribing physician's office to obtain authorization to refill the prescription. Ms. Kao stated that she did not perform drug utilization review on each prescription for the patient in question, but she has improved since that time. The patient told Ms. Kao that she had to go on a business trip, and Ms. Kao stated that she believed the patient.

The committee expressed concern that the pharmacy computer did not alert Ms. Kao that the prescriptions were being filled too soon.

Ms. Kao responded that the computer would alert her if she tried to bill the insurance carrier, however the patient often paid cash. Ms. Kao stated that she did not review the drug utilization report for every prescription for this patient. Ms. Kao added that she always obtained authorization from the prescribing physician to refill the prescription.

The committee stated that this was a patient that was in the pharmacy on a regular basis, that Ms. Kao must have known this patient on sight. The committee expressed concern as to how Ms. Kao could not realize that she had dispensed a toxic dosage to this patient.

Ms. Kao responded that she did not perform drug utilization on every prescription for this patient. Ms. Kao added that now she performs drug utilization on every prescription.

M/S/C: Nelson/Elsner

The committee accepted the appearance of Nancy Lee, RPH 25073, Christina Kao, RPH 47816, and Rite Aid #5893, PHY 43940; (a) the matter will be made a part of the record of Nancy Lee, RPH 25073, Christina Kao, RPH 47816, and Rite Aid #5893, PHY 43940; (b) Christina Kao, RPH 47816 is cited and fined \$1000, for failure to perform drug utilization review as required. No further action will be taken at this time.

4. Lobelia Rubin
RPH 32732, PIC

CI 1998 16087

Rite Aid #6041
Fortuna, CA
PHY 42498

Bruce Wiswell, Pharmacy Development Manager
Richard Martland, Attorney

Lobelia Rubin and Rite Aid #6041 were requested to appear at the Northern Compliance Committee as the result of an investigation that revealed that on May 29, 1998 RPH Rubin failed to properly reconstitute a Cedax prescription and also failed to provide patient consultation for a new prescription.

On September 17, 1998, a violation notice was issued to Lobelia Rubin and Rite Aid #6041 for violation of:

- Business and Professions Code section 4301 – Unprofessional conduct.
- Business and Professions Code section 4076 (a) (9) – The expiration date of the effectiveness of the drug dispensed.
- California Code of Regulations section 1716 – Variation from a prescription.
- California Code of Regulations section 1707.2 – Duty to consult.

The following violations are charged to Rite Aid #6041:

- Business and Professions Code section 4301(o) – Unprofessional conduct.
- Business and Professions Code section 4076 (a) (9) – Prescription container requirements for labeling.
- Business and Professions Code section 4113 (a) – Every pharmacy shall designate a pharmacist-in-charge and within 30 days thereof, shall notify the board in writing of the identity and license number of that pharmacist and the date he or she was designated.
- Business and Professions Code section 4305 (a) – Any person who has obtained a license to conduct a pharmacy, shall notify the board within 30 days of the termination of employment of any pharmacist who takes charge of, or acts as manager of the pharmacy.

Ms. Rubin stated that she remembers this incident because the woman was very impatient because she had a sick child. Mr. Rubin received a call from the woman two hours later where the woman reported that the suspension was too thick. Ms. Rubin stated that at that time she understood that the patient would return the medication to the pharmacy.

The committee explained that the complainant believes that Ms. Rubin added more water to the suspension.

Ms. Rubin explained that the next day when the woman returned the medication, Ms. Rubin re-printed the label and refilled the medication. Ms. Rubin added that she put it in a different style of bottle to show the woman what the medication looked like.

Ms. Rubin further explained that she fully consulted with the woman as to her child's medication. Ms. Rubin added that she remembers giving the woman all the warning signs that the child might be allergic to the medication.

M/S/C: Nelson/Elsner

The committee accepted the appearance of Lobelia Rubin, and Rite Aid #6041. The matter will be made a part of the record of Lobelia Rubin, RPH 32732, and Rite Aid #6041, PHY 42498. No further action will be taken at this time.

5. Vito Maurantonio
RPH 19355, PIC

CI 1998 16335

Horsnyder Pharmacy
Watsonville, CA
PHY 36104

Leo Leal, Owner

Vito Maurantonio, and Horsnyder Pharmacy were requested to appear at the Northern Compliance Committee Meeting as the result of an investigation that revealed that a pharmacy technician at Horsnyder Pharmacy was stealing Vicodin and Vicodin ES.

This is a violation of:

- Health and Safety Code section 11173 – No person shall obtain or attempt to obtain controlled substances by fraud.
- Business and Professions Code section 4301 – Unprofessional conduct.
- Business and Professions Code section 4202 – Pharmacy technician, license requirements for education, experience, board regulations, criminal background check, discipline.

The committee expressed concern as to how the pharmacists did not catch that an excessive amount of Vicodin was coming into the pharmacy and Vicodin was not being dispensed to balance the acquisition.

Mr. Leal responded that the medication was ordered on the electronic ordering system. The pharmacy is opened twelve hours per day, so one pharmacist does not work the entire shift.

Mr. Maurantonio added that the pharmacists have taken a proactive approach to monitoring the inventory on all controlled substances.

The committee asked Mr. Leal if as an absentee owner, does he ever drop in and do spot checks of the inventory.

Mr. Leal explained that he works in a store in Santa Cruz. He explained that on average he drops into the pharmacy twice a week to check on the pharmacy.

The committee accepted the appearance of Vito Maurantonio, and Horsnyder Pharmacy; (a) the matter will be made a part of the record of Vito Maurantonio, RPH 19355, and Horsnyder Pharmacy, PHY 36104. No further action will be taken at this time.

6. Michael Trone
RPH 27432, PIC

CI 1997 15631

O. E. "Bud" Fox
RPH 18885

Fair Oaks Pharmacy
Stockton, CA
PHY 40389

Richard Giambruno, Owner

Michael Trone, O. E. "Bud" Fox, Richard Giambruno, and Fair Oaks Pharmacy were requested to appear at the Northern Compliance Committee Meeting as the result of an investigation that revealed that RPH Fox dispensed Coumadin 4mg on a prescription calling for Coumadin 1mg.

On May 25, 1999, a violation notice was issued to Fair Oaks Pharmacy and O. E. "Bud" Fox for violation of:

- Business and Professions Code section 4301 – Unprofessional conduct.
- California Code of Regulations section 1716 – Variation from a prescription.

The committee expressed concern with regard to how this error occurred.

Mr. Fox responded that he could offer no defense or explanation as to how he made the error. Mr. Fox explained that he only worked relief in this pharmacy on three previous occasions, and four days before the error occurred his wife was diagnosed with Alzheimer's disease. Mr. Fox added that in retrospect his emotional state was such that he should not have been working at all.

The committee expressed concern as to how consultation was offered on delivered prescriptions.

Mr. Fox explained that this patient had been taking Coumadin prior to this prescription. There was a change in the dosage on this prescription, but consultation was performed over the phone if the patient had any questions the patient was encouraged to call the pharmacy.

The committee admonished Mr. Fox stating that he should have be proactive, he should have called the patient to explain the change in his dosage.

M/S/C: Nelson/Elsner

The committee accepted the appearance of Michael Trone, O. E. “Bud” Fox, and Fair Oaks Pharmacy; (a) the matter will be made a part of the record of Michael Trone, RPH 27432, O. E. “Bud” Fox, RPH 18885, and Fair Oaks Pharmacy, PHY 40389. No further action will be taken at this time.

7. Paramjit Randhawa
RPH 45898, PIC

12:00 p.m.

Phillip Webb
RPH 40310

Mark Karpoff
RPH 31675

Priscilla Martinez
TCH 22610

Walgreens
Clovis, CA
PHY 39108

Chris Dige, Pharmacy Supervisor

Paramjit Randhawa, Phillip Webb, Mark Karpoff, Priscilla Martinez, and Walgreens were requested to appear at the Northern Compliance Committee Meeting as the result of an investigation that revealed that on pharmacy technician dispensed a prescription without proper supervision by a pharmacist. The prescription called for clonidine 0.1mg, but was misfilled with clonazepam 1mg. Ancillary personnel were observed providing prescriptions to patients without the pharmacist present.

On July 16, 1998, a violation notice was issued to Paramjit Randhawa and Walgreens for violation of:

- Business and Professions Code section 4301(n) – Unprofessional conduct.
- Business and Professions Code section 4081 (a) – All records of manufacture and of sale, acquisition, or disposition of dangerous drugs or dangerous devices shall be at all times during business hours open to inspection.

The following violations are charged to Paramjit Randhawa:

- Business and Professions Code section 4116(a) - No person other than a pharmacist, an intern pharmacist, an authorized officer of the law, or a person authorized to prescribe shall be permitted in that area, place, or premises described in the license...However, a pharmacist shall be responsible for any individual who enters the pharmacy for the purposes of...performing clerical, inventory control, housekeeping, delivery, maintenance, or similar functions relating to the pharmacy...

- Business and Professions Code section 4115(a) - Notwithstanding any other provision of law, a pharmacy technician may perform packaging, manipulative, repetitive, or other non-discretionary tasks, only while assisting, and while under the direct supervision and control of, a pharmacist.
- California Code of Regulations section 1714(d) - Each pharmacist while on duty shall be responsible for the security of the prescription department, including provisions for effective control against theft or diversion of dangerous drugs and devices, and records for such drugs and devices.

The following violations are charged to Phillip Webb and Mark Karpoff:

- California Code of Regulations section 1707.2 - (a) A pharmacist shall provide oral consultation to his or her patient or the patient's agents in all care settings: (1) Upon request.

Ms. Martinez responded that she does not remember the incident.

The committee expressed concern with regard as to how Ms. Martinez knows when consultation is required.

Ms. Martinez responded that everyone from the cashier to the pharmacist knows that all new prescriptions require consultation. All prescriptions are marked as new or refill prescription. This mark appears on the label.

The committee advised those present that a large red consultation stamp would bring a lot more attention to the fact that consultation is required.

Mr. Dige responded that the stamps have already been ordered.

The committee expressed concern as to the pharmacist leaving the licensed area.

Ms. Randhawa explained that she had left the pharmacy to use the bathroom. She stated that before she left the pharmacy she checked that no patients were waiting, and that there were no new prescriptions ready to be dispensed.

The committee expressed concern that there are no initials on the container label to establish who filled the prescription.

Ms. Randhawa responded that with the pharmacy's new computer system an electronic log is kept.

The committee advised those present that per California Code of Regulations section 1793.7 states that the pharmacist must hand write his or her initials the prescription label. Also when a technician fills the prescription the pharmacist that checks the work of the technician must hand write his or her initials on the label.

Ms. Randhawa responded that she was unaware that her initials were required, and she will change her procedure.

The committee strongly admonished those present stating that judging from the facts in this case, it appears that supervision of ancillary staff is woefully inadequate, and that closer supervision of the ancillary staff is indicated for this pharmacy.

M/S/C: Nelson/Elsner

The committee accepted the appearance of Paramjit Randhawa, Phillip Webb, Mark Karpoff, Priscilla Martinez, and Walgreens; the matter will be made a part of the record of Paramjit Randhawa, RPH 45898, Phillip Webb, RPH 40310, Mark Karpoff, RPH 31675, Priscilla Martinez, TCH 22610, and Walgreens, PHY 39108. No further action will be taken at this time.

There being no additional discussion, the meeting was adjourned at 12:30 p.m.